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Low Fistula in Ano Treatment using Diode Laser 980nm

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Abstract: Background: Anal fistula is an anorectal condition with over 90% of cases being cryptoglandular in origin and occurring after anorectal abscesses. The traditional method of treatment of an anal fistula is by excision or de roofing the tract awaiting complete healing.. Aim: The aim of this study is to assess the efficacy of diode laser 980 nm in the treatment of low fistula in ano. Methods: The study was performed between June 2019 to end of September 2019, at the institute of laser for postgraduate study in Baghdad university. A cohort of ten male patients with a provisional diagnosis of low type anal fistula were selected for this study and treated by interstitial photothermal therapy of fistula epithelium by diode laser 980nm . They were ageing from 21-45 years. Results: The mean operative time was 18.9 minutes (range of 12-25) minutes. All patients discharged after procedure to their home. No pain is presented by seven patients. Only three patients reported a mild pain and occasional need for a pain killer. No patient complained of incontinence anytime during postoperative period. The mean time for closure of the fistulae was 12.7 days(range of 7-18 days). Conclusions: The procedure described in this work indicate that it may be possible to affect healing of a low anal fistula tract by mere photocoagulation of the tract without excision or deroofing.

Introduction

A fistula-*in-ano*, or anal fistula, is a chronic abnormal communication, usually lined to some degree by granulation tissue, which runs outwards from the anorectal lumen (the internal opening) to an external opening on the skin of the perineum or buttock (or rarely, in women, to the vagina).Anal fistula is an anorectal problem with over 90% of patients being cryptoglandular in base origin and occurring after anorectal abscesses (Nelson 2002). The feared complications associated with the treatment of anal fistulas are fecal incontinence(&flatulence) due to anal sphincter damage, and fistula recurrence (Rojanasaku 2009). According to Parks classification, fistulas are classified into four main groups; intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric (Parks 1976) . Generally, even the simplest fistulas types have a limited risk for continence disorders. The reported incontinence rates vary up to 40% depending on the type of fistula and the surgical management applied. Even with no anal sphincter damage, most cases experience minor anal incontinence in the early postoperative follow up period (Malouf 2002) . Fistulotomy is a gold standard in a treatment of anal fistulas, but the recovery rate is >90% (Hall 2014).However, cases treated with a fistulotomy are at risk of developing postoperative anal sphincter dysfunction. This risk is higher in females and patients with complicated fistulas, preoperative incontinence,

recurrence, or past anorectal surgery (Garcia 1996). In addition, studies have shown that fistulotomy, even in cases of simple fistulas, may cause functional dysfunction (anal incontinence) in some patients, that adversely affects patients' life quality (Dudukgian 2011). The risk of continence dysfunction increases when using fistulotomy in the treatment of "high" fistulas due to the anal sphincter damage that may occur during surgery (Atkin 2011). For this, various "sphincter-sparing" techniques including the use of fibrin glue and anal fistula plugs (AFP), ligation of the intersphincteric fistula tract (LIFT), and the anorectal advancement flap (ARAF) have been described to minimize concerns about functional outcomes in the treatment of fistulas (Adegbola 2017). These approaches were initially promising, but the success rates reported revealed conflicting results (Adegbola 2017). None has been universally acceptable as the gold standard approach for surgical treatment of high fistula FiLaC (fistula laser closure) was first used by Wilhelm in 2011 for the treatment of fistula in ano (Wilhelm 2011). This approach involved completely removing the whole length of the fistula tract and closure of the internal opening of the fistula by using a laser diode source and a radial laser probe. The FiLaC most important feature is that the laser tip used does not damage the sphincters and other structures. The FiLaC procedure was designed to simultaneously eliminate both the anal gland/crypt and the epithelial layer of the fistula through photothermal effect, while also closing the internal and external fistula openings. The main causes of recurrence of fistula in other techniques such as fibrin plugs and bioprosthetic plugs include overlooked or untreated internal openings, overlooked side tracts, insufficient drainage of the intersphincteric space, and/or residues of fistula epithelium and granulation tissue (Wałęga 2014).

Patients and Methods

A cohort of ten patients with a provisional diagnosis of low type anal fistula were selected for this study. All of them were males, ageing from 21-45 years. All patients were diagnosed by clinical examination and fistulogram. History of peri anal abscess were surgically drained in six patients. The rest of four patients admitted history of a painful peri anal swelling that was ruptured spontaneously. The average duration between symptoms and presentation was 7 months (range of 2-12 months).

In all of the ten patients, clinical examination reveal a single external fistula opening lying at variable positions and distances from the anal verge. The average distance was 3.75 cm(range of 2.5-5 cm). Anorectal digital examination can identify a palpable internal opening in nine patients.

All selected patients had no significant chronic medical illness (Table 1).

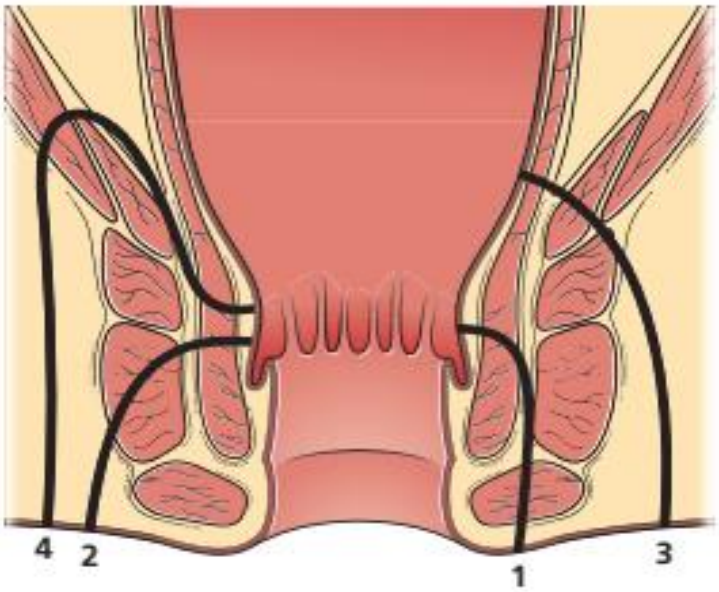


Fig. (1): Types of anal fistula (Parks classification): 1, intersphincteric, 2, trans-sphincteric, 3, supersphincteric and 4, extrasphincteric primary track.

Table (1): Details of ten patients

Patient No	Age (ys)	Duration (months)	Present history	Past history	Clinical finding External opining	Internal Opining by PR
1	21	2	Spontaneous Rupture of Peri anal Abscess	Negative	Post. at 6 o'clock. 2 cm. from anal verge	Positive
2	38	8	surgically drained Abscess	Negative	ant. At 2 o'clock. 3 cm from anal verge.	Positive
3	30	6	surgically drained Abscess	Negative	Post. At 5o'clock 3cm from anal verge	Negative
4	35	10	Spontaneous Rupture of Peri anal Abscess	Negative	Ant. At 11 o'clock 4 cm. From anal verge.	Positive
5	27	4	surgically drained Abscess	Negative	Ant. At 1 o'clock 3 cm. From anal verge.	Positive
6	41	9	surgically drained Abscess	Negative	Ant. At 11o'clock 3 cm from anal verge	Positive
7	45	5	Spontaneous Rupture of Peri anal Abscess	Negative	Post. At 7 o'clock 5 cm from anal verge.	Positive
8	32	12	Spontaneous Rupture of Peri anal Abscess	Negative	Post. At 6 o'clock 3.5cm from anal verge.	Positive
9	24	7	surgically drained Abscess	Negative	Post. At 7 o'clock 2 cm from anal verge.	Positive
10	31	4	surgically drained Abscess	Negative	Post. At 8 o'clock 4cm from anal verge.	Positive

Each patient was involved in the procedure after full explanation and discussion regarding the nature of the procedure, the possible advantages and disadvantages, and complications expected. Each patient was asked to sign an " informed consent" indicating his agreement. The procedure done under local anesthesia using emla 10.5 % topical cream 30 minutes then to followed by 10 cc of Lidocain 1% with adrenalin 1: 100000 injection along fistula tract and perianal region . Prior to local anesthesia, safety precautions were checked for patient , doctor and assistant from laser hazards, patient was put in knee elbow position during local anesthesia and throughout operation time, the operative field was mopped with 10% povidoniodin solution, sterile towels wetted with sterile saline solution were applied to isolate the operative field. Figure 2

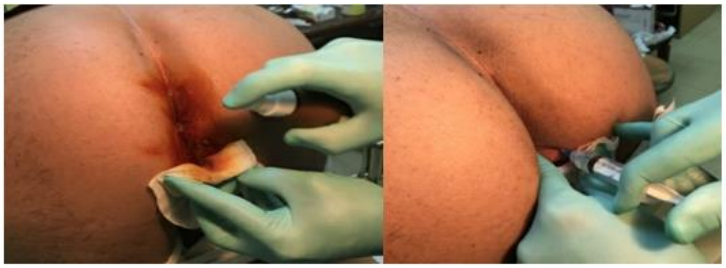


Fig. (2) : Povidoniodin 10 % spraying and Lidocain injection

The laser system used was a "Velas60"surgical diode laser. It essentially incorporated a class IV GaAlAs (Gallium Aluminum Arsenide) diode laser emitting at a wave length range of 940 + 10 nm (near infra-red) with a power output at laser aperture ranging from 1-60 watts. It can be operated at a continuous or pulsed mode. Other technical specifications are illustrated in Table 2.2 (36)

Table 2: Technical specifications of the Velas60

Specification	**Details**
Laser type	GaAlAs laser diode
Wave length	940 + 10 nm.
Housing	Fiber – coupled diode laser
Power out put	1-60 W
Treatment modalities	cw, single pulsed, repetitive pulse
Pulse	pulse width :10 ms–1s. pulse repetition rate:1Hz- 100Hz
Transmission system	contact fiber of 400µm, 600µm, 1000µm with SMA905; noncontact : fiber and tip.
Pilot Operation interface	diode laser of 650 nm, power < 5mW, adjustable brightness color LCD touch screen
Power supply	230 Vac, 5 A, 50 Hz
Laser class	4
Safety classification	class 1 type B
Cooling	Air.
Fuse	T 250 V 5 A.
Waterproof level	IPX1
Foot switch waterproof level	IPX8

"velas60 " is manufactured in the PRC.(fig.2).

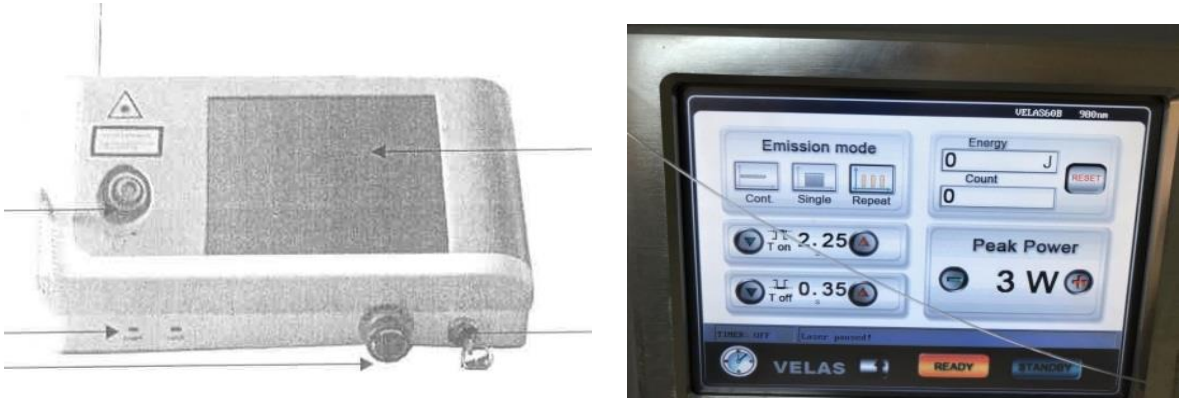


Fig. (3): "Velas60" Surgical laser

The procedure started with gentle and gradual dilatation of the anal verge up to four fingers, the internal opening of the fistula was reassessed and its site was identified by digital examination and directly viewed by sideway opened split proctoscope.

A blunt ends stainless steel metallic fistula probe was used to identify the whole fistula tract starting from the external opening, along the whole tract and out through the internal opening Figure 4.

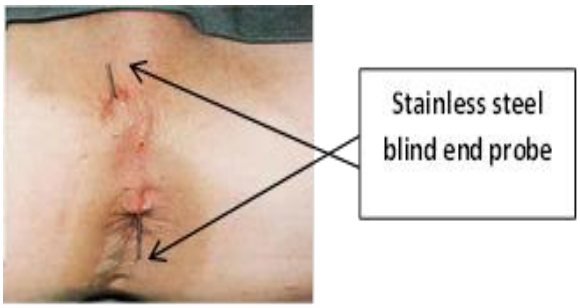


Fig. (4) : Fistula tract completely probed

The sterile optical fiber was introduced to the operative field .The rear end of it was given to the assistant who removed the SMA (SubMiniature version A) cover and fix the standard SMA connector to the output port (laser aperture) while the laser power switch was off. Then the main power switch was put "on", the power indicator was noticed. Then the laser was put on the "stand by" mode and a "repeated mode " operation mode was selected by "mode select" switch with 2.25 second on and 0.35 second off. The pre determined desired power of 5 Watts was set .Before starting operating the laser, a notice was given to the attendant , and the "ready" mode was displayed on the screen. The tip protector was then removed and the aiming beam (red light) was demonstrated . By pressing on the "foot switch", laser was fired and tested on sterile "gloves cover". Laser firing was terminated at this point.

The optical fiber started to be introduce to the fistula tract from its external orifice along its whole tract reaching its internal orifice guided by previous identification of the tract by metallic probe and palpating optical fiber pathway along the fistula tract by finger guidance and assisted by direct visualization through proctoscopic examination . By gently and steadily pushing the optical fiber end that was emerging out of the internal orifice using the left hand, the right hand was guiding the optical fiber tip to negotiate the fistula tract through the external opening, along the whole fistula tract, and through the internal opening, just out of the anal verge Figure 5.

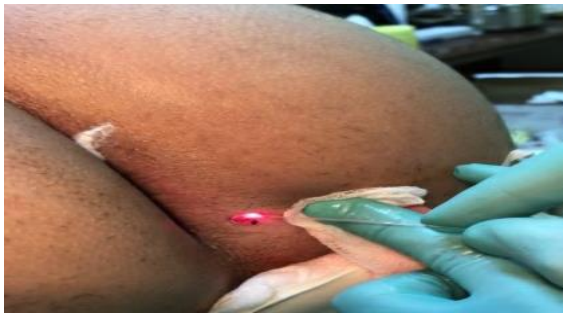
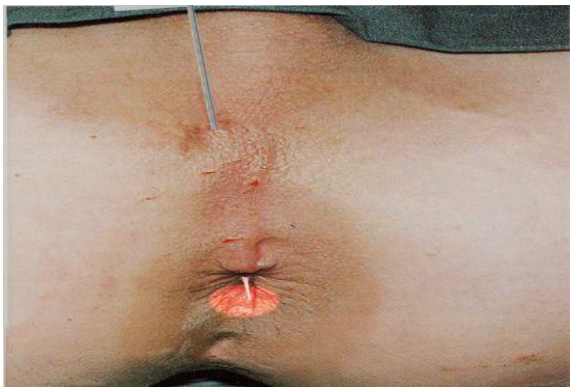


Fig. (5): Optical fiber threaded along fistula tract.

The gloved assistant fingers were keeping a steady retraction on the anal verge opposite the internal ring. With this, the whole length of the fistula is now threaded by the optical fiber. Great gentleness was needed and the flexibility of the optical fiber was not "over used" in order to avoid the accidental "breaking" of the optical fiber inside the fistula tract.

The optical fiber tip was now pulled back to disappear just at the internal orifice and while the assistant was keeping retraction on the anal verge, another notice was given and the laser was fired again by the foot switch Figure 6.



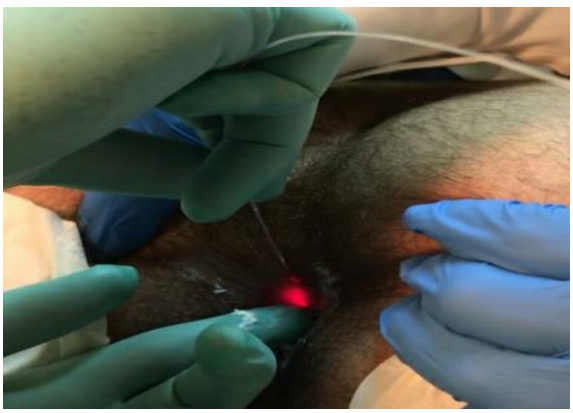


Fig. (6) : Firing laser prior to retrograde pulling.

Pre carbonization of the tip was not needed. At this point, the optical fiber was pulled "slowly and gently" in a retrograde manner at a rate of 0.5 cm./ min. The procedure continued at this rate until the whole optical fiber was out of the fistula except for the tip which was left for extra 10 seconds at the external opening prior to pulling it out terminating the procedure (Figures 7, 8, and 9 below).

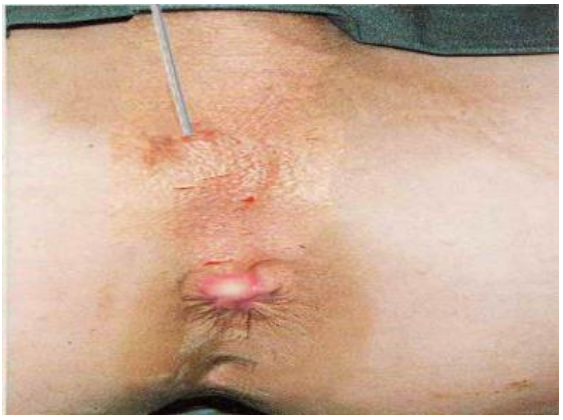
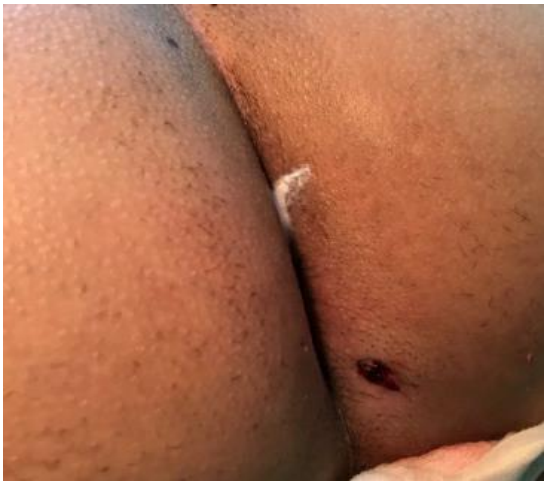


Fig. (7) : Start of photocoagulation of the tract



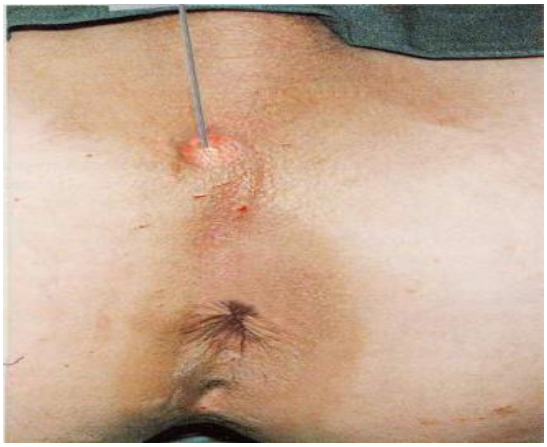


Fig. (8) : Photocoagulation of the external opining

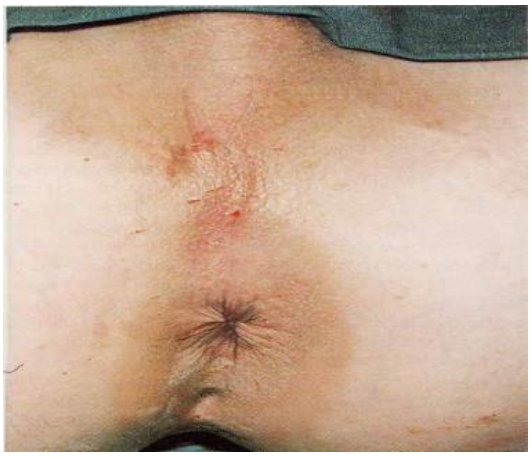


Fig. (9) : Photocoagulation of the anal fistula completed

With the parameters mentioned above, the total exposure time for each patient was entirely dependent on the length of the fistula treated (table.3). The mean exposure time was 7.17 mins.(range of 4.17-10.17 min.).

Table 3: Laser exposure time for each fistula

Patient number	Fistula length (cm)	Exposure time (min.)*
1	**2**	**4.17**
2	**3**	**6.17**
3	**3**	**6.17**
4	**4**	**8.17**
5	**3**	**6.17**
6	**3**	**6.17**
7	**5**	**10.17**
8	**3.5**	**7.17**
9	**2**	**4.17**
10	**4**	**8.17**

*N.B; An extra 10 seconds(0.17min.) of exposure to the external opining of each fistula.

The diode laser was found easy to use in all cases. Instruction for use were easy to follow. Setting up the laser took approximately 2 minutes. Because of the laser small size, it could be moved easily and a foot pedal and an optical fiber were all that were needed to attach before the unit was operated. Reading information displayed on the screen during the procedure was difficult while looking at an angle of less than 40^0. The optical fiber was easy to clean for re use, it could then be recoiled and , packaged and resterelized with either cidex or by autoclaving. Sterilization indicators were placed within each package to ensure

sterility. No complications were associated with the operative procedure.

The reasons behind selection of cases of low anal fistula for this procedure were the availability compared with cases of complicated high and recurrent anal fistulae, in addition, it is the operator opinion that it would be unwise to select complicated cases of high or recurrent anal fistulae because the effect of laser photocoagulation of the fistula tract need to be verified on cases were the possibility of uncontrolled damage to the sphincter is remote.

Selection of the diode laser for this procedure was dependent on the availability, portability, and applicability of the optical fiber, which was the necessary accessory to transfer laser energy to the treatment site.

Safety measures were applied easily. The theater staff was cooperative, labels were available on the theater gate and the machine, and enough goggles were always available to the attendant during the procedure. No accident regarding laser safety was recorded.

Results : The results of the assessment of the evaluation parameters are presented in Table 4.

Table (4): Results of evaluation parameters in 10 patients

No	Date of operation	Operative time(min.)	Time to discharge	Fistula closure(days)	*Postoperative pain	Follow up(wks)
1	26/6/2019	12	Immediately	7	--	13
2	26/6/2019	18	Immediately	12	--	13
3	3/7/2019	16	Immediately	10	--	12
4	17/7/2019	25	Immediately	15	+	10
5	31/7/2019	15	Immediately	9	+	8
6	31/7/2019	18	Immediately	14	--	8
7	7/8/2019	25	Immediately	18	+	7
8	7/8/2019	22	Immediately	17	--	7
9	21/8/2019	15	Immediately	10	--	4
10	21/8/2019	23	Immediately	15	--	4

(--) no pain; (+) mild;(++)moderate;(+++) sever post operative pain.

Operative time was considered from the moment of initial fistula probing till the termination of laser delivery to the tissue. The mean operative time was 18.9 minutes (range of 12-25) minutes. All patients discharged immediately to their home.

Evaluation of the post operative pain was done during the follow- up period. No pain is experienced by seven patients. Only three patients reported a mild pain and occasional need for a pain killer. No patient complained of incontinence anytime during postoperative period. Follow up was conducted to assess the time needed for healing and closure of the fistula. The disappearance of the discharge and closure of the fistula were considered as signs of healing. The mean time for closure of the fistulae was 12.7 days(range of 7-18 days). The follow up period could only asses the short term results of the treatment. Intermediate and long term recurrences need a longer follow up period to asses. Recurrence is announced when the fistula start discharging again after being closed. There were no recurrences reported within the follow up period. The mean follow up period was 8.6 weeks(range of 4-13weeks).No patient was lost on follow up period. Along the follow up period mentioned, no gross changes were noted in the overlying skin along the coagulated tract and palpation of the area detected no abnormalities in the form of contractures, hardness or parasthesia.

Discussion

Comparing the results of photo coagulation of the fistula tract (using laser) with the results of other conservative approaches shows that, with laser use, operative time was shorter, minimal postoperative pain, no hospitalization stay, and a quicker return to work was reported. Fistula closure time again was short. These results match those for fibrin glue application except for fistula closure time, which cannot be compared because, in effect, there is an immediate closure of the fistula with fibrin glue application. The short-term recurrence rate of photocoagulation was comparable with that for all the methods mentioned.

The follow up period in this study can only assess the short-term results of this procedure. According to the criteria for "fistula closure", there were no recurrences within the follow up period. To assess intermediate and long term recurrence, a longer follow up period (up to 2 years) is needed.

The amount of laser energy deposited in the tissue was directly related to the length of the fistula tract treated. At the fixed rate of retrograde application and the fixed power chosen, the longer the fistula tract the more the exposure time and the more the laser energy deposited in the treatment site. An extra 10 seconds (0.17min.) of laser application to the external opining was necessary to coagulate the pouting granulation tissue, thus encouraged healing and closure of the external opening. It seems that at the parameters chosen, coagulation of a well-formed fistula tract is safe, with no apparent damage to the nearby sphincter muscles. None of the patients in the study complained of postoperative incontinence. Because of absence of gross changes in the area treated, it seems that nothing precludes repeating the procedure or resorting to any of the conventional methods in case of failure and recurrence. The parameters mentioned in the study are definitely reproducible in any future study with or without modifications.

"Velase 60" (diode laser 980 nm device used) was found portable, easy to operate, and no technical difficulties were experienced during the use of the laser or the accessory.

The results of the assessment of "how far the procedure is indicated" shows that laser treatment is possible but in competition with other techniques because the study was performed only on cases of low anal fistula, and the small number of cases did not allow for statistical analysis of the results. Other methods may compete with laser until a proper analysis of the results against control cases can be obtained in a future extended study. On the other hand, "feasibility" indicates that laser application is excellent when defocused interstitial application through an Orb tip optical fiber is performed.

Conclusions

The procedure described in this work indicates that it may be possible to affect healing a low anal fistula tract by mere photocoagulation of the tract without excision or deroofing. It can be considered as a conservative non surgical approach to the treatment of anal fistula. Healing and closure of the fistula tract may be attributed to the coagulative destructive effect of the laser. Within the chosen parameters for application, there is no evidence of damage to the anal sphincter, less postoperative pain, immediate discharge to home, and short fistula closure time. The follow up period assesses only the short-term results. The procedure can be repeated in case of failure and its application dose not preclude the application of any other conventional procedure. No statistical analysis has been attempted because of the small number of cases operated upon. Because of the fixed parameters, the results of this work are reproducible. The only conservative approach with which results of the procedure can be matched is the application of fibrin glue after curettage of the tract.

The laser used is found a useful surgical tool. It is portable, easy to operate, and safe when recommended applications are adhered to, the accessory chosen is useful for interstitial application.

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الخلاصة: إن الطريقة التقليدية لعلاج ناسور المخرج هي استئصال قناة الناسور كليا أو فتح سقف هذه القناة انتظاراً لشفائها . هذه الدراسة تحقق في نتائج استخدام طريقة التخثير الضوئي المجرد لقناة الناسور دون استئصالها أو فتح سقفها وذلك من خلال تسليط ضوء الليزر تراجعيا داخل باطن القناة باستخدام الليف الضوئي المغذى من قبل ليزر الدايود ذي الطول الموجي 980 نانومتر والذي يشع في حدود الأشعة تحت الحمراء القريبة .تم اختيار عصبة من عشرة مرضى من الرجال متوسط أعمارهم 33 عاما ويعانون من ناسور المقعد واطئ المستوى لغرض إجراء هذه الطريقة.كان متوسط المسافة بين الفتحة الخارجية للناسور و بين المخرج هو 3.75سم وفي مواقع مختلفة حول فتحة المخرج . أجريت العملية تحت التخدير الموضعي. كان متوسط الزمن اللازم لأجراء العملية هو 18.9 دقيقة وكان متوسط مدة التعرض لشعاع الليزر هو 7.17دقيقة. أظهرت نتائج هذه الدراسة أن الزمن اللازم لأجراء العملية اقصر ,وان مغادرة المريض مباشرة ,مع وقت اقصر لشفاء الناسور وألم طفيف أو معدوم بعد العملية ,وذلك مقارنه بالطرق التقليدية . ضمن مدة المتابعة ومتوسطها 8.6 أسابيع, لم يظهر دليل على حدوث عدم سيطرة على فتحة المخرج أو حالة رجوع للناسور المعالج. لقد كانت إمكانية تطبيق هذه الطريقة ممتازة باستخدام الليف الضوئي .إن هذه الطريقة يمكن فقط مقارنتها بطريقة حقن جوف القناة بالصمغ الفايبريني والتي قد تنافس طريقة التخثير الضوئي لباطن القناة . تستنتج الدراسة انه باستخدام التخثير الضوئي لباطن القناه قد يكون من الممكن شفاء ناسور المخرج واطئ المستوى دون الحاجة للاستئصال او فتح سقف الناسور وانه لا توجد دلائل على حدوث ضرر لصمام المخرج باستخدام مقاييس شعاع الليزر التي تم اختيارها مسبقا. توصي الدراسة مستقبلا بزيادة عدد المرضى المعالجين بهذه الطريقة وذلك للحصول على تحليل إحصائي مناسب للنتائج .من المفضل شمول حالات ناسور المخرج عالي المستوى والمضاعف والراجع. توصي الدراسة أيضا بتمديد فترة المتابعة لتقييم حالات الرجوع ذات الأمد المتوسط والطويل وتوصي أيضا باستخدام ليزر الدايود ذي الطول الموجي 1470 نانومتر مستقبلا.